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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,951	03/17/2004	William F. DeGrado	1694.0630003	2895

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005

EXAMINER
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CHONG, YONG SOO

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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10/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 10/801,951	<b>Applicant(s)</b> DEGRADO ET AL.	
	<b>Examiner</b> Yong S. Chong	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 15-49, 54-56, 62, 63 and 65-73 is/are pending in the application.
- 4a) Of the above claim(s) 1, 15, 49, 54-56, 62, 63, 65 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-48, 67-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Application***

This Office Action is in response to applicant's arguments filed on 8/20/2007. Claim(s) 2-14, 50-53, 57-61, 64 have been cancelled. Claim(s) 69-73 have been added. Claim(s) 1, 15-49, 54-56, 62-63, 65-73 are pending. Claim(s) 16-18, 24-27, 48-49, 67 have been amended. Claim(s) 1, 15, 49, 54-56, 62-63, 65-66 have been withdrawn. Claim(s) 16-48, 67-73 are examined herein.

Applicant's amendments have rendered the rejection of the last Office Action moot, therefore hereby withdrawn. The following new rejection will now apply.

Examiner reminds Applicant that as stated in the last Office Action, the species requirement has been withdrawn, therefore the full scope of the claims will be examined.

### ***Claim Objections***

Claim 73 is objected to because of the following informalities: the term "heterarylene" is misspelled. Appropriate correction is required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-48, 67-73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-27, 29, 37 of U.S. Patent No. 7,173,102 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because a method of killing microorganisms by contacting a surface with a compound of formula II is disclosed. The specific embodiments of formula II as well as the motivation to administer to an animal in need of treatment for a microbial infection are discussed below.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 16-48, 67-73 are rejected under 35 U.S.C. 103(a) as being obvious over DeGrado et al. (US Patent 7,173,102 B2).

The instant claims are directed to a method of treating a microbial infection in an animal in need thereof by administering a pharmaceutical composition comprising an oligomer of formula II.

DeGrado et al. disclose amphiphilic polymers that inhibit the growth of microorganisms in contact with the surface or in areas adjacent to said biocidal surface (abstract, claims 26 and 29). The term "microorganism" includes bacteria, algae, fungi, yeast, mycoplasmas, parasites and protozoa (col. 9, lines 12-14). Testing of the bacterial efficacy has been performed in mammals with these polymers in water (col. 24, lines 57-64, example 5-6). DeGrado et al. teaches a need to design these polymers with reduced toxicity to birds, fish, mammals, and other higher organisms. Furthermore, any object that is exposed to or susceptible to bacterial or microbial contamination can be treated with these polymers, particularly in food and health care, for example for the use in contact lenses. Both pets and agronomic animals are exposed to and harbor a variety of infectious pathogenic organisms that can cause disease in animals or humans (col. 27, lines 1-28).

A preferred polymer or oligomer is represented by a compound of formula I or II, where X can be NR<sub>3</sub>, NHNH (where R<sub>3</sub> is hydrogen), O, S; Y can be CO; both A and B are independently optionally substituted o-, m-, p-phenylene, or optionally substituted

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heteroarylene wherein one of A and B is substituted with a polar (P) group and a nonpolar (NP) group and the other of A and B is substituted with neither a polar nor a nonpolar group; NP can be R<sub>4</sub>, -U-(CH<sub>2</sub>)<sub>p</sub>-R<sub>4</sub>, wherein R<sub>4</sub> can be hydrogen, C1-C2 alkyl, C3-C18 branched alkyl, P is a polar group selected from hydroxyethoxymethyl or -U-(CH<sub>2</sub>)<sub>p</sub>-V, where U is O or S and V can be amino, guanidine; p is 0 to 8; and m is 2 to at least 500; R<sub>1</sub> is (i) -y-C, (ii) H, or (iii) R<sub>1</sub> and R<sub>2</sub> together are a single bond; R<sub>2</sub> is -x-(CH<sub>2</sub>)<sub>p</sub>-W wherein W is H, V, N-maleimide, phenyl optionally substituted with up to three substituents selected from the group consisting of V, alkyl, carboxy, etc (claims 1, 4-27, 29, 37). Representative "heterocycles" include pyridine, cyclic guanidines, pyrazole, pyrazoline, pyrrolidine, piperidine, piperazine, etc. (col. 10, lines 3-12).

However, DeGrado et al. fail to specifically disclose administration to an animal infected with a microorganism.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer to an animal infected with a microorganism a pharmaceutical composition comprising a compound of formula I or II as disclosed by DeGrado et al.

A person of ordinary skill in the art would have been motivated to administer to an animal infected with a microorganism a pharmaceutical composition comprising an oligomer of formula I or II because: (1) DeGrado et al. give the general teaching that the disclosed oligomers inhibit the growth of microorganisms; (2) DeGrado et al. teach that testing of the bacterial efficacy of the disclosed oligomers have been performed in mammals; (3) DeGrado et al. teach a need to design the disclosed oligomers with

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reduced toxicity to birds, fish, mammals, and other higher organisms; (4) DeGrado et al. teach that any object that is exposed to or susceptible to bacterial or microbial contamination can be treated with the disclosed oligomers; and (5) DeGrado et al. give the general teaching that both pets and agronomic animals are often exposed to and harbor a variety of infectious pathogenic organisms that can cause disease in animals or humans. Therefore, a person of ordinary skill in the art would have had a reasonable expectation of success in treating a microbial infection in an animal by administering a pharmaceutical composition comprising the preferred oligomers disclosed in DeGrado et al.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER